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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/593,111	09/14/2006	Kevin Cink	1193	9382
23408 7590 10/13/2009 GARY C. COHN, PLLC P. O. Box 313			EXAMINER	
			NEGRELLI, KARA B	
Huntingdon Valley, PA 19006			ART UNIT	PAPER NUMBER
			1796	
			NOTIFICATION DATE	DELIVERY MODE
			10/13/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail $\,$ address(es):

garycohn@seattlepatent.com

Application No. Applicant(s) 10/593,111 CINK ET AL. Office Action Summary Examiner Art Unit KARA NEGRELLI 1796 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 01 September 2009. 2a) This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 24-32 is/are pending in the application. 4a) Of the above claim(s) 25 and 26 is/are withdrawn from consideration. 5) Claim(s) _____ is/are allowed. 6) Claim(s) 24 and 27-32 is/are rejected. 7) Claim(s) _____ is/are objected to. 8) Claim(s) _____ are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abevance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. Attachment(s)

1) Notice of References Cited (PTO-892)

Notice of Draftsperson's Patent Drawing Review (PTO-948)

Information Disclosure Statement(s) (PTO/S5/08)
 Paper No(s)/Mail Date ______.

Interview Summary (PTO-413)
 Paper No(s)/Mail Date.

6) Other:

Notice of Informal Patent Application

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EXTRUDED POLYLACTIDE FOAMS BLOWN WITH CARBON DIOXIDE

DETAILED ACTION

Response to Amendment

 The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

- Any rejections stated in the previous Office Action and not repeated below are withdrawn.
- 3. The new grounds of rejection set forth below are necessitated by applicant's amendment filed on September 1, 2009. In particular, claims 25-26 have been cancelled, Claim 24 has been amended to depend from new added process claims to incorporate the crystallinity of previously presented claim 25, and new claims 27-32 have been added.
- It is noted that the newly introduced limitations were not present at the time of the preceding action. For this reason it is proper to make the present action FINAL.

Claim Rejections - 35 USC § 103

 The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

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6. Claims 24, 27-30, and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hammel et al. (US 5,134,171) in view of Shinohara (JP 2003-073495). The rejection is over JP 2003-073495, however, for convenience the machine translated English equivalent will be cited below and is attached.

- 7. Hammel et al. teach polyhydroxy acid foam materials comprising polylactic acid and carbon dioxide (column 2, lines 34-38 and column 2, line 60 column 3, line 11). The polymer composition of the polyhydroxy acid foam having from 50-97%, and preferably from 85 to 96% of the L enantiomer of lactic acid, with additional lactic acid units being of the D enantiomeric configuration (column 4, lines 31-39). The polyhydroxy foam is produced using an extrusion system (Example 1, column 6, lines 35-61). Furthermore, the formed foam is subjected to heat treatment after the extrusion process (Example 1, column 6, lines 56-57). Hammel et al. further teach that at least 90% of the foam cells are closed after shaping (column 3, lines 43-45) or above 50% of the cells are closed after shaping. Hammel et al. further teach that the lactic acid-containing polymer may comprise long chain branching (column 2, lines 45 column 3, line 5).
- 8. With regard to the amount of closed cells, it is well settled that where the prior art describes the components of a claimed compound or compositions in concentrations within or overlapping the claimed concentrations a prima facie case of obviousness is established. See *In re Harris*, 409 F.3d 1339, 1343, 74 USPQ2d 1951, 1953 (Fed. Cir 2005); *In re Peterson*, 315 F.3d 1325, 1329, 65 USPQ 2d 1379, 1382 (Fed. Cir. 1997); *In re Woodruff*, 919 F.2d 1575, 1578 16

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USPQ2d 1934, 1936-37 (CCPA 1990); In re Malagari, 499 F.2d 1297, 1303, 182 USPQ 549, 553 (CCPA 1974).

- 9. Hammel et al. teach that the same amounts of L and D enantiomers of polylactic acid are present in the resin to be foamed as are taught in the instant specification. The polymer of Hammel et al. composition of the polyhydroxy acid foam having from 50-97%, and preferably from 85 to 96% of the L enantiomer of lactic acid, with additional lactic acid units being of the D enantiomeric configuration (column 4, lines 31-39). The polyhydroxy foam may comprise a carbon dioxide foaming agent and is produced using an extrusion system (Example 1, column 6, lines 35-61). Furthermore, the formed foam is subjected to heat treatment after the extrusion process. See example 1, column 6, lines 57-58).
- 10. In one example of Hammel et al., 25 lbs/hr of blowing agent is incorporated into 500 lbs/hour of molten polylactic acid (85% L, the remaining 15% being D/L). This corresponds to 5 wt% blowing agent. Because the blowing agents to be used may comprise carbon dioxide, and because an example teaches using 5 wt % blowing agent, it would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate 5 wt% carbon dioxide blowing agent into the molten polylactic acid polymer of Hammel et al. The molten polymer is further heat treated after being formed (column 6, lines 57-58). Because the composition may comprise the same amounts of L and D configurations of polylactic acid, and may comprise 5 wt% carbon dioxide, and because the composition is exposed to heat after being formed, as taught in the

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instant application, one of ordinary skill in the art would reasonably expect the composition to have the same crystallinity as taught in the instant application. Case law holds that a material and its properties are inseparable. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

- 11. Hammel et al. do not expressly teach that the foam comprises from 5 to 15% or more specifically from 7 to 11% carbon dioxide or that the foam has a crystallinity of 13-24 J/g as measured by differential scanning calorimetry.
- 12. However, Shinohara teaches an amorphous polylactide foam comprising from 2 to 20 wt% carbon dioxide foaming agent (paragraph [0002]), said foam of which may have a crystallinity, as measured by differential scanning calorimetry, of 15 or more J/q (paragraph [0011]).
- 13. It would have been obvious to use the amount of carbon dioxide taught by Shinohara et al. in the invention of Hammel et al. in order to improve the "die shape reproducibility" and weld nature of the polylactic acid resin (Shinohara et al., paragraph (00041).
- 14. Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hammel et al. (US 5,134,171) and Shinohara (JP 2003-073495) and further in view of Morita et al. (US 5,238,968).
- 15. Hammel et al. and Shinohara teach the compositions as applied to claims 24 and 27-30 but do not expressly teach that the extrusion temperature is from 70° to 140°C.

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- 16. However, Morita et al. teach a process foamed material comprising a composition polylactic acid which is composed of 85 to 100% by mole of L-lactic acid unit and from 0 to 15% by mole of the antipode unit of each lactic acid (column 3, 1-5), from 0.2 to 10 parts by weight (based on 100 parts by weight polylactic acid-based resin) of a blowing agent which may be carbon dioxide (column 6, lines 23-35), process of which further comprises extruding the composition at a temperature of from 100°C to 270°C (column 6, lines 50-54) which overlaps the instantly claimed extrusion temperature of instant claim 31. It is well settled that where the prior art describes the components of a claimed compound or compositions in concentrations within or overlapping the claimed concentrations a prima facie case of obviousness is established. See In re Harris, 409 F.3d 1339, 1343, 74 USPQ2d 1951, 1953 (Fed. Cir 2005); In re-Peterson, 315 F.3d 1325, 1329, 65 USPQ 2d 1379, 1382 (Fed. Cir. 1997); In re-Woodruff, 919 F.2d 1575, 1578 16 USPQ2d 1934, 1936-37 (CCPA 1990); In re Malagari, 499 F.2d 1297, 1303, 182 USPQ 549, 553 (CCPA 1974).
- 17. It would have been obvious for one of ordinary skill in the art at the time the invention was made to use the extrusion temperatures taught in Morita et al. in the processes of Hammel et al. and Morita et al. because extrusion temperature lower than 100°C makes extrusion unstable and tends to cause overload while temperatures over 270°C are unfavorable because decomposition of the lactic acid based polymer becomes violent (Morita et al., column 6, lines 55-59). All references teach foamable compositions which may comprise the required amounts (as taught in the instant specification) of L and D enantiomers

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of lactic acid, a carbon dioxide blowing agent, and extrusion and therefore are analogous art.

Response to Arguments

- Applicant's arguments filed September 1, 2009have been fully considered but they are not persuasive.
- 19. Applicant argues that crystallinity is not an inherent property of polylactide but rather is contingent upon factors such as the presence of carbon dioxide or a post foaming heat treatment. Applicant argues that Hammel et al. describe carbon dioxide as one of several blowing agents and in a particular example teach only using 0.44% carbon dioxide in a molten polylactide resin. Applicant further argues that Hammel et al. does not teach a heat-annealing step and that therefore, the manner in which Hammel's extruded foam is made differs from the instant application. Applicant cites example 4 and further asserts that Hammel does not mention crystallinity or any desire to develop crystallinity.
- 20. Applicant's argument is not persuasive. Hammel et al. teaches both the presence of carbon dioxide and subjected the foamed material to heat after it is produced (See column 3, lines 35-37 and column 6, lines 57-58). While Example 4 of Hammel does not exemplify 5 wt% carbon dioxide, this does not negate a finding of obviousness under 35 USC 103 since a preferred embodiment such as an example is not controlling. Rather, all disclosures "including unpreferred embodiments" must be considered. In re Lamberti 192 USPQ 278, 280 (CCPA 1976) citing In re Mills 176 USPQ 196 (CCPA 1972). Therefore, it would have

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been obvious to one of ordinary skill in the art to utilize a blowing agent in the amount of 5% in the molten polylactic acid composition (said blowing agent of which may comprise carbon dioxide) given that Hammel et al. teaches each one. Said composition would inherently possess the crystallinity taught in instant claim 24. Case law holds that a material and its properties are inseparable. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

- 21. In response to applicant's argument that Hammel et al. does not describe crystallinity, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985
- 22. Applicant argues that Shinohara (JP 2003-073495) is different from Hammel and the present invention in that it describes a bead foaming process. Applicant states that this is a fundamentally different process than extrusion foaming and produces a different type of product. Applicant argues that bead foams are made by forming lightly crosslinked polymer beads, impregnating them with a blowing agent, placing the beads in a mold, and gently heating the beads so that they stick together to form a molded piece. Applicant asserts that bead foams of this type are used to make articles such as disposable drinking cups and inexpensive food and beverage coolers which are designed for temporary
- 23. Applicant's argument is not persuasive. The fact that foam particles are bead shaped does not render them incapable of being used in extrusion

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processes or incapable of being used to produce articles other than drinking cups and inexpensive food and beverage coolers which are for temporary use. Foam beads may be coalesced, extruded, and used to produce articles used for sound absorption, thermal insulation, vibration dampening materials, cushion packaging, automobile parts, medical devices, as well as several other applications. See, for example, Chaudhary et al., US 6,395,791, column 24, lines 38-48; column 25, lines 37-45; and column 28, lines 16-40 for various examples of articles produced by molding foamed beads.

- 24. Furthermore, the composition of Shinohara is used in an extrusion process (paragraph [0011]). The applicant's assertion that weld nature and die shape reproducibility are characteristic problems with bead foam processes but are of no importance in extrusion processes is erroneous. "Weld nature" is not a characteristic of only foam *beads* and does not only refer to how well particles stick together in a bead foam process. Rather, "weld nature" is also applicable to foam strands, sheets, boards, or other extruded foam shapes. Die shape reproducibility is not contingent upon foam materials being only of a bead shape. In fact, "die shape" is particularly applicable to extrusion. No evidence has been provided to support the applicant's position.
- 25. The Hammel at al. and Shinohara references are analogous in that both teach processes for forming foam products comprising polylactic acid and carbon dioxide blowing agent which are using an extrusion process. Because both are the same field of endeavor, one skilled in the art would look to Shinohara et al. as quidance as to ways to modify Hammel.

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26. As to the temperature description of Shinohara as described by applicant on page 7 of the remarks filed September 1, 2009, the temperature is concerned with impregnating a particle with carbon dioxide, not to the temperature at which a mixture comprising the materials may be extruded. See paragraph [0017]. For fusing foam particles together, steam is used. One of ordinary skill in the art would recognize that steam is generally 100°C or higher. After particles are fused together, they are melt needed together (molten mixture) and extruded into shapes. See paragraphs [0024] and [0031]. Furthermore, in response to applicant's arguments against Shinohara individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See In re Keller, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); In re Merck & Co., 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Note that while Shinohara et al. do not disclose all the features of the present claimed invention. Shinohara et al. is used as teaching reference. and therefore, it is not necessary for this secondary reference to contain all the features of the presently claimed invention, In re Nievelt, 482 F.2d 965, 179 USPQ 224, 226 (CCPA 1973), In re Keller 624 F.2d 413, 208 USPQ 871, 881 (CCPA 1981). Rather this reference teaches a certain concept, a polylactic acid resin with a given crystallinity and carbon dioxide content, and in combination with the primary reference, discloses the presently claimed invention.

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Conclusion

27. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL.
See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

28. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KARA NEGRELLI whose telephone number is (571)270-7338. The examiner can normally be reached on Monday through Friday 8:00 am EST to 5:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Randy Gulakowski can be reached on (571)272-1302.

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The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/KARA NEGRELLI/ Examiner, Art Unit 1796

/Randy Gulakowski/ Supervisory Patent Examiner, Art Unit 1796